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### **REMARKS**

The present application is directed to compositions comprising a combination of electroprocessed materials and substances, and methods of making and using the same. Claims 1, 5-6, 9 and 24-35 are currently pending in this application. Claim 5 is withdrawn as being directed to a non-elected species. Claims 10-23 are cancelled without prejudice. Applicants reserve the right to pursue the subject matter of Claims 10-23 in a separate application. Claims 2-4, 7-8 and 10-23 are cancelled. Claims 1 and 6 are currently amended. Claims 24-35 are new. Amendments herein do not introduce any new matter and support for the amendments and new claims are found throughout the specification. Favorable consideration of the currently pending claims is respectfully requested in light of the following remarks.

#### ***Claim rejections under 35 U.S.C. §112, first paragraph***

In the Non-Final Office Action mailed July 26, 2005, the Examiner rejected Claims 1-9 under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. Applicants respectfully submit that the amendments to the Claims overcome the rejection.

Applicants respectfully submit that the claims as amended herein define electroprocessed materials, natural materials and synthetic materials. Accordingly, Applicants respectfully assert that the amendments overcome the rejection under 35 U.S.C. §112, second paragraph, and request its withdrawal.

#### ***Claim rejections under 35 U.S.C. §112, second paragraph***

In the Non-Final Office Action mailed July 26, 2005, the Examiner rejected Claim 8 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants respectfully submit that the amendments to the Claims overcome the rejection.

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Claim 8 is canceled herein, rendering moot this rejection. Accordingly, Applicants respectfully assert that the rejection of Claim 8 under 35 U.S.C. §112, second paragraph has been overcome and request its withdrawal.

***Claim rejections under 35 U.S.C. §102(b)***

***Coffee et al.***

In the Non-Final Office Action mailed July 26, 2005, the Examiner rejected Claims 1, 2, 4 and 6-8 under 35 U.S.C. §102(b) as being anticipated by Coffee *et al.*, (WO 98/03267 see equivalent U.S. 6,252,129, hereinafter Coffee). The Examiner states Coffee discloses electrohydrodynamically making solid, partially solid or gel-like compositions of fibers that incorporate or have a core of an immiscible substance such as a biologically active ingredient or cells for applying to skin, a wound, a burn or body cavity. The Examiner concluded these fibers may form a mat or web and may be prepared from fibrin or collagen. Claims 2, 4, 7 and 8 are canceled, rendering their rejection moot.

Applicants respectfully submit that the amendments to the Claims overcome the rejection. Applicants respectfully submit Coffee fails to teach or suggest an electroprocessed composition as recited in amended Claim 1.

Regarding new Claim 25, the electroprocessed material comprises a combination of one or more natural materials and one or more polymers. Applicants concur with the Examiner (as stated on page 9 of the Office Action dated July 26, 2005), and respectfully submit Coffee fails to teach or suggest an electroprocessed composition comprising a combination of one or more natural materials and one or more polymers.

Regarding new Claim 33, Applicants respectfully submit Coffee fails to teach or suggest an electroprocessed composition comprising electroprocessed collagen fibers comprising a repeated banding pattern, wherein the repeated banding pattern occurs at a spacing of about 65 nm to 67 nm.

Accordingly, Applicants respectfully assert they have overcome the rejection and request its withdrawal.

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Martin et al.

In the Non-Final Office Action mailed July 26, 2005, the Examiner rejected Claims 1 and 6-9 under 35 U.S.C. §102(b) as being anticipated by Martin *et al.*, (U.S. 4,043,331, hereinafter Martin). The Examiner states Martin discloses making a fibrillar mat. The Examiner states various polymers may be used to form the fibers. The Examiner also concludes various immiscible substances such as biological components can be incorporated within the mat. The Examiner concludes Martin discloses crosslinking of water soluble polymers. Claims 7 and 8 are canceled, rendering their rejection moot.

Applicants submit that the amendments to the Claims overcome the rejection. Applicants respectfully assert Martin fails to teach or suggest an electroprocessed composition comprising one or more natural materials selected from amino acids, peptides, denatured peptides, polypeptides, proteins, carbohydrates, lipids, nucleic acids, glycoproteins, lipoproteins, glycolipids, glycosaminoglycans and proteoglycans as recited in amended Claim 1. Martin fails to teach or suggest each element of the claimed subject matter and cannot therefore anticipate the claimed invention. Accordingly, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. §102(b).

Doshi et al.

In the Non-Final Office Action mailed July 26, 2005, the Examiner rejected Claims 1, 2 and 6-8 under 35 U.S.C. §102(b) as being anticipated by Doshi *et al.*, ("electrospinning process and applications of electrospun fibers", J. Electrostatics 35:151-160, 1995, hereinafter Doshi). The Examiner states Doshi discloses making three dimensional compositions of electrospun fibers from solutions of water-soluble polymers, biopolymer and liquid crystalline polymers. The Examiner states immiscible substances such as an insecticide, a wound treating composition or blood may be incorporated into the composition. The Examiner also concludes composite materials may be produced when the spinning solutions are changed successively so that layers of different polymers are deposited on top of each other. Claims 2, 7 and 8 are canceled, rendering their rejection moot.

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Applicants respectfully assert that the amendments to the Claims overcome the rejection. Applicants respectfully submit Doshi fails to teach or suggest a therapeutic or cosmetic substance as recited in amended Claim 1. Doshi fails to teach each element of the claims and cannot therefore anticipate the claimed invention.

Accordingly, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. §102(b).

***Claim rejections under 35 U.S.C. §102(e)***

In the Non-Final Office Action mailed July 26, 2005, the Examiner rejected Claims 1-4 and 6-8 under 35 U.S.C. §102(e) as being anticipated by Murphy *et al.*, (U.S. US 2002/0172705, hereinafter Murphy) as evidenced by Koseki *et al.*, (US 5,922,356, hereinafter Koseki). The Examiner states Murphy discloses a composition comprising electroprocessed fibers, collagen and an electroprocessed synthetic polymer that is produced by culturing fibroblasts in a cell or tissue culture vessel that is electrostatically charged. The Examiner states the fibroblasts produce collagen as an extracellular matrix. The Examiner states Koseki discloses that the diameter of collagen fibers reconstituted in vivo is less than 50 nm, while the diameter of collagen fibers in vivo is about 10-130 nm. Applicants respectfully traverse. Claims 2, 4, 7 and 8 are canceled, rendering their rejection moot.

Applicants respectfully submit the instant application discloses electroprocessing of solutions to produce electroprocessed materials (see Examples and Figures). The instant application does not teach or suggest electrostatically charging a cell growth surface.

Furthermore, the instant application teaches that the electroprocessed compositions may be made using electrospinning, electroaerosol, electrospraying or electrosputtering techniques, or any combination thereof (see page 3, lines 11-14). Applicants respectfully submit electrostatic charging of a cell growth surface is outside of the scope of electroprocessing as defined in the instant application. Applicants respectfully submit Murphy discloses induction of fibroblasts to produce fibers, such as collagen.

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Applicants respectfully submit Murphy fails to teach, suggest or motivate one of ordinary skill in the art to make the claimed compositions for at least the foregoing reasons.

Additionally, the deficiencies of Murphy are not satisfied by Koseki because Koseki is directed to the production of sustained release formulations that require a glycosaminoglycan as an essential element. In contrast, the instant application does not require a glycosaminoglycan.

Furthermore, Koseki fails to teach or suggest electroprocessing in any form. Consequently, Koseki is silent with regard to electroprocessing one or more natural materials or one or more synthetic materials, and a therapeutic substance or a cosmetic substance as claimed herein. Applicants respectfully submit Murphy, alone, or in combination with Koseki fail to teach, suggest or motivate one of ordinary skill in the art to make the claimed invention. Accordingly, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. §102(e).

***Claim rejections under 35 U.S.C. §103(a)***

In the Non-Final Office Action mailed July 26, 2005, the Examiner rejected Claims 1-4 and 6-9 under 35 U.S.C. §103(a) as being unpatentable over Coffee, Martin, Doshi, and Murphy, (already of record) in view of Mechanic (US 5,332,475). The Examiner stated Coffee, Martin, Doshi, and Murphy fail to disclose electroprocessed compositions comprising at least one natural material and at least one synthetic material. Furthermore, the Examiner stated Coffee, Martin, Doshi and Murphy fail to disclose electroprocessed compositions comprising cross-linked natural polymers. Claims 2-4, 7 and 8 are canceled, rendering their rejection moot.

The Examiner concluded it would be obvious to one of ordinary skill in the art at the time of the invention to crosslink the fibrous mat of Coffee and Doshi as suggested by Martin, because Coffee, Martin and Doshi make electroprocessed fibrous mats for similar purposes. The Examiner further concluded it would have been *prima facie* obvious to crosslink the electroprocessed fibrous mats for the expected increased strength and stability

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of crosslinking. The Examiner stated it would therefore have been obvious to one of ordinary skill in the art at the time of the invention to crosslink electroprocessed protein materials for the advantages disclosed by Mechanic.

Applicants respectfully assert that the amendments to the Claims overcome the rejection. Applicants respectfully submit the remarks provided above under Claim rejections under 35 U.S.C. §102(b) and 102(e) are repeated here.

Applicants respectfully submit it is unclear from the Office Action if the Examiner meant to refer to the teachings of Mechanic, rather than Martin, in the above 35 U.S.C. §103(a) rejection. Applicants have responded to the rejection as such. If Applicants have erred in their interpretation of the rejection, Applicants kindly request the Examiner contact the undersigned attorney of record.

Dependent Claim 9 refers to crosslinking. Applicants respectfully assert one of ordinary skill in the art would not be motivated to derive the composition of Claim 1 (and therefore dependent Claim 9) based on the teachings of Mechanic, alone, or in combination with Coffee, Martin, Doshi and Murphy. Applicants submit one of ordinary skill in the art would not be motivated to modify the teachings of Doshi, Martin, Murphy or Coffee based on the teachings of Mechanic because Mechanic is directed to a method of crosslinking collagen in the presence of a photo oxidative catalyst. Applicants respectfully submit the claimed invention, as amended, is directed to electroprocessed materials comprising one or more natural materials, one or more synthetic materials, and a therapeutic or cosmetic substance. Mechanic fails to provide any motivation to crosslink a natural or synthetic material in the absence of a photo oxidative catalyst. Furthermore, Mechanic fails to teach a therapeutic or cosmetic substance as recited in amended Claim 1. Accordingly, Applicants assert they have overcome the rejection under 35 U.S.C. §103(a) and request its withdrawal.

***Double Patenting-Obviousness type***

In the Non-Final Office Action mailed July 26, 2005, the Examiner provisionally rejected Claims 1-9 under the judicially created doctrine of obviousness-type

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double patenting as being unpatentable over Claims 9-17 and 25-46 of copending Application No. 09/991,373; Claims 1-2 of copending Application No. 10/409,682; Claims 1-17 of copending Application 10/447,670; Claims 1-4 of copending Application No. 10/630,624. The Examiner stated the claims are not patentably distinct because the instant claims recite a genus of compositions, while the copending applications recite, respectively,

an engineered tissue comprising electroprocessed collagen and cells;

a composition comprising an electroprocessed material and a substance; wherein the electroprocessed material is a fiber having a diameter of 20 microns or less;

a matrix comprising electrospun collagen fibers having a diameter of 30 nm to 10 microns; and

electroprocessed collagen produced by various techniques.

Applicants respectfully submit that the amendments to the Claims overcome the rejection. Applicants respectfully submit the independent claims, as amended, represent patentably distinct inventions over the prior art and co-pending applications. Additionally, none of the pending independent claims comprise limitations regarding fiber diameter size or engineered tissue as recited in the copending applications. Accordingly, Applicants do not wish to file a terminal disclaimer at this time. Applicants respectfully request withdrawal of the rejection under the judicially created doctrine of obviousness-type double patenting.

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### CONCLUSION

Based upon the amendments and remarks provided above, Applicants believe the pending Claims are in condition for allowance. A Notice of Allowance is therefore respectfully solicited.

No additional fees are believed due; however, the Commissioner is hereby authorized to charge any additional fees that may be required, or credit any overpayment, to Deposit Account No. 11-0855.

If the Examiner believes any informalities remain in the application that may be corrected by Examiner's Amendment, or there are any other issues that can be resolved by telephone interview, a telephone call to the undersigned attorney at (404) 815-6500 is respectfully solicited.

Respectfully submitted,



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